



PULMOTECT



Pulmotect receives FDA approval to commence two Phase-2 trials targeting COVID-19

Proceeds of \$12 million Series B to fund development

Houston, TX (May 5, 2020) – Pulmotect, Inc., a clinical-stage biotechnology company, has received approval from the U.S. Food & Drug Administration (FDA) to initiate two COVID-19 Phase-2 clinical trials of its innate immune stimulating drug PUL-042. The Company plans to start accrual within the next week at up to twenty U.S. sites. The trials are for the prevention of infection with SARS-CoV-2 and the prevention of disease progression in patients with early COVID-19 disease. Funding for the trials came from the final closing of the Company's offering of Series B Preferred stock in March.

"Both clinical trials are placebo-controlled to objectively evaluate safety and efficacy," said Dr. Colin Broom, CEO of Pulmotect. "In the first study, up to four doses of PUL-042 or placebo will be administered to 200 subjects by inhalation over a ten day period to evaluate the prevention of infection and reduction in severity of COVID-19. In the second study, 100 patients with early symptoms of COVID-19 will receive the treatment administered up to three times over six days. In both trials, subjects will be followed up for 28 days to assess the effectiveness and tolerability of PUL-042."

Pulmotect's PUL-042 drug harnesses the power of the innate immune system, the front line of disease defense, to fight off a wide range of respiratory infections. Initially targeted to treat respiratory complications of cancer patient treatment, PUL-042 was well tolerated in three Phase1/2a clinical trials in the U.S. and the U.K. Additionally, PUL-042 has demonstrated compelling protection against a broad range of respiratory pathogens, including the coronaviruses that cause MERS and SARS in preclinical mice models. "We have always considered PUL-042 to have the potential for the prevention and treatment of emerging epidemics and pandemics like the one we currently face," said Broom. "Our development program to prevent respiratory infection and complications in cancer patients would support this potential, however, given the current pandemic, we have mobilized our resources towards directly evaluating the effect of PUL-042 against SARS-CoV-2 infection."

Broom's deep expertise bringing new drugs through the FDA approval process was critical in bringing this work – and the nimble shift in focus -- to fruition. Pulmotect Chairman Leo Linbeck III observed that "the Pulmotect team has

performed phenomenally over the past weeks: performing study design, regulatory submissions, clinical trial start-up activities and manufacturing the additional product in a fraction of the time ordinarily required.”

PUL-042, a synergistic combination of two toll-like receptor agonists, activates the lungs’ first line of defense, the surface immune system. As microbes, including viruses, land on the epithelial cells of the lung lining, they are destroyed on-contact by antimicrobial peptides and reactive oxygen species (ROS), including superoxide’s, that are released by epithelial cells. With a positive signal of activity and favorable tolerability from these initial trials, the technology is positioned to quickly accelerate into pivotal trials, with the potential to pursue Emergency Use Authorization (EUA) to help treat and prevent the spread of the COVID-19 pandemic and contribute to the global economic recovery. With robust pre-clinical protection already shown against multiple pathogens, PUL-042 also could function as a long-term broad-spectrum solution for future similar pandemics, bioterror attacks, and other potential indications.

Pulmotect has partnered with CTI Clinical Trial and Consulting to conduct the two clinical trials entitled:

- A Phase 2 Multiple Dose Study to Evaluate the Efficacy and Safety of PUL-042 Inhalation Solution in Reducing the Infection Rate and Progression to COVID-19 in Adults Exposed to SARS-CoV-2
- A Phase 2 Multiple Dose Study to Evaluate the Efficacy and Safety of PUL-042 Inhalation Solution in Reducing the Severity of COVID-19 in Adults Positive for SARS-CoV-2 Infection

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About Pulmotect

Pulmotect is developing PUL-042, a clinical stage, first-in-class, inhaled, immunomodulatory agent. A synergistic agonist that amplifies the innate immune defenses of the lung epithelial mucosa to provide broad-spectrum, pathogen-agnostic protection against respiratory infections. Invented at UT MD Anderson Cancer Center/Texas A&M University, PUL-042 has patents issued in 10 countries, both as a stand-alone composition of matter product and in combination with antivirals. PUL-042 R&D has been supported by the National Institutes of Health (NIAID, NIGMS), the Cancer Prevention and Research Institute of Texas (CPRIT), and other funding agencies. For more information, visit www.pulmotect.com.

About Fannin Innovation Studio

Houston-based Fannin Innovation Studio is an early-stage life sciences development group focused exclusively on commercializing biotech and medtech technologies. Fannin creates and manages start-ups to develop internal and in-licensed programs. Fannin has over a dozen active programs, including three in clinical development. For more information, visit www.FanninInnovation.com, come by the Studio at 3900 Essex Lane -- Suite 575 in Houston, or email us at innovate@fannininnovation.com.

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